IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION **THIS DOCUMENT RELATES TO:** **ALL PLAINTIFFS LISTED IN PLAINTIFFS' MOTION**	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

ETHICON'S MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE CERTAIN OPINIONS AND TESTIMONY OF DOUGLAS GRIER, M.D.

Douglas Grier, M.D. is an experienced urologist specializing in female pelvic medicine and surgery. He has performed over 1,000 mesh surgeries to treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP), including those utilizing TVT products (TVT, TVT-O, and TVT-Secur), Prolift, and Prolene Soft Mesh. Dr. Grier has educated and trained hundreds of surgeons in these techniques. Dr. Grier also has treated mesh complications and performed mesh revisions. He has performed research in the field of incontinence and bladder disorders, and contributed to studies on the use of TVT abdominal guides and the TVT world registry. Throughout his career, he has kept abreast of issues in his field by review and study of the relevant literature.

Despite this extensive career, Plaintiffs seek to exclude Dr. Grier's opinions that: (1) the designs of TVT products, Prolift, and Prolene Soft Mesh are safe and effective for use in patients; (2) the benefits of the TVT products, Prolift, and Prolene Soft Mesh outweigh their risks based in part on his complication rate with polypropylene transvaginal mesh devices; and

(3) the Instructions for Use (IFU) for the TVT products, Prolift, and Prolene Soft devices adequately warn of their risks. Plaintiffs' motion should be denied because:

- **Dr. Grier is qualified to offer the challenged opinions.** Dr. Grier's extensive clinical and research background make him well qualified to give opinions on the safety and efficacy of TVT products, Prolift, and Prolene Soft Mesh, as well as the IFUs for these products.

- **Dr. Grier's design opinions are supported by a reliable methodology.** Relying upon clinical experience and review of relevant literature is a reliable method for forming opinions on the safety and efficacy of the TVT products, Prolift, and Prolene Soft Mesh.

- **Dr. Grier's clinical experience is admissible to support his risk/benefits opinions.** Dr. Grier's extensive clinical experience, including his observations of the incidence of complications he sees in his practice, supports his opinion that the benefits of TVT products, Prolift, and Prolene Soft Mesh outweigh their risks.

Plaintiffs' challenges to Dr. Grier's opinion testimony are meritless under Rule 702 and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Defendants Ethicon, Inc. and Johnson & Johnson (Ethicon) therefore ask that Plaintiffs' motion be denied.

ARGUMENTS AND AUTHORITIES

I. Dr. Grier's Opinions on the Safety and Efficacy of the Designs of the TVT Products, Prolift, and Prolene Mesh Are Admissible.

A. Dr. Grier Is Qualified to Provide Safety and Efficacy Opinions.

A physician's "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders qualifies him to render opinions on [product design], notwithstanding his lack of expertise in the particular areas of product design or biomaterials." *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D.W. Va. 2013), on reconsideration in part (June 14, 2013) (finding Dr. Shull qualified, but excluding his design opinion on reliability grounds). Further, a physician's "experience removing polypropylene transvaginal mesh devices and performing revision and excision procedures qualifies him" to give product design opinions. *Winebarger v.*

Boston Scientific Corp., No. 2:13-cv-28892, 2015 WL 1887222, at *6 (S.D.W. Va. Apr. 24, 2015).

Dr. Grier has the necessary qualifications to opine that the designs of the TVT products, Prolift, and Prolene Soft Mesh are safe and effective for use in patients. Specifically, Dr. Grier is a urologist with an expertise in urologic surgery and the materials used in urologic surgery. Ex. 1, Grier 3/22/16 Dep. Tr. 329:6-10. He has specialized in female pelvic medicine and surgery for over 15 years. *Id.* at 82:14-19; Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 1-2. Before this litigation, at least 50 percent of Dr. Grier's practice was related to the treatment of SUI and POP. Ex. 1, Grier 3/22/16 Dep. Tr. 145:23-146:1.

He has performed native-tissue surgical procedures and surgical procedures involving mesh, including Ethicon's TVT and TVT-O, TVT-Abbrevo, and TVT-Secur mid-urethral slings, AMS Monarch, Uretex by Bard, Vesica in situ sling, Stamey cystourethropexy, MMK, and Burch procedures. Ex. 1, Grier 3/22/16 Dep. Tr. 333:24-334:9; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 2. All told, he has performed over 1,000 TVT procedures, including procedures implanting the TVT-O, TVT-Exact, and TVT-Abbrevo. Ex. 1, Grier 3/22/16 Dep. Tr. 31:15-21, 333:24-334:9. He also has performed surgeries utilizing Prolift and Prolene Soft mesh. Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 2; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 2. Besides performing surgical implant procedures, he also treats mesh complications and has performed mesh-removal surgeries for exposed TVT mesh. Ex. 1, Grier 3/22/16 Dep. Tr. 142:16-20, 143:20-144:13, 146:5-11.

In addition to his clinical background, Dr. Grier also has an extensive teaching and research background. He has taught over 300 courses for advanced surgical training of physicians for conditions such as stress urinary incontinence and pelvic organ prolapse. Ex. D to

Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 2; Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 2. And he has conducted research in the field of incontinence and bladder disorders, and has contributed to studies on the use of TVT abdominal guides and the TVT world registry published in the Journal of Urology in 2011. Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 2. To keep abreast of issues in his field, he regularly reviews the relevant medical literature and has done so for the past ten to fifteen years. Ex. 1, Grier 3/22/16 Dep. Tr. 50:14-20.

Dr. Grier's extensive experience with pelvic-floor disorders and the use of mesh to treat these disorders uniquely qualifies him to render opinions on the safety and efficacy of mesh product design. Although he is not an engineering expert, Dr. Grier is well versed on the use and placement of vaginal mesh based on his extensive training and experience. Ex. 1, Grier 3/22/16 Dep. Tr. 67:14-17. The law does not require Dr. Grier to have expertise designing mesh products to be qualified to give an opinion on the safety and efficacy of these products. *In re C.R. Bard, Inc.*, 948 F. Supp. 2d at 612; *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D. W.Va. 2014) (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products)

B. Dr. Grier Utilized a Reliable Methodology in Forming His Safety and Efficacy Opinions.

This Court has made clear that a physician can draw upon his clinical experience and review of relevant literature to give an opinion on the risk/benefit profile of polypropylene mesh. *Winebarger*, 2015 WL 1887222, at *7. Dr. Grier seeks to offer the same kind of opinion here—*i.e.*, that the benefits of the TVT, Prolift, and Prolene Soft Mesh products outweigh their risks. He bases that opinion on his extensive clinical experience performing hundreds of SUI and POP mesh surgeries and removing mesh devices from patients. Ex. 1, Grier 3/22/16 Dep. Tr. 143:20-

144:13, 145:23-146:11, 333:24-334:9; Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 1-2; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 1-2; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 1-2. Dr. Grier's opinion is also based on his education, training, teaching, extensive review of high-level, peer-reviewed literature (including comparing complications discussed in the literature with those seen in his practice), studies, professional society position statements, and ongoing discourse with colleagues. Ex. 1, Grier 3/22/16 Dep. Tr. 331:12-332:17, 336:11-20, 338:18-351:6; Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 7-19, 22-24; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 6-15, 17-19; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 11-23, 25-30; Ex. E to Pls.' Mot. (Dkt. 2022-5), Grier TVT-Secur Report at 11-27, 31-35.

There is no requirement under *Daubert* that Dr. Grier review internal company design documents for his methodology to be reliable as Plaintiffs argue. Nor has this Court ever required as much. Although Plaintiffs rely on *Winebarger* to support their argument, that reliance is misplaced. In that case, Dr. Shull sought to opine that the company had failed to follow its own internal protocols and that those protocols were lacking, even though he had never seen any standard operating procedures for the company's medical device development or any of the internal design protocols. *Winebarger*, 2015 WL 1887222, at *14. Dr. Shull's methodology was thus lacking "a necessary piece of data" and unreliable "regardless of the literature he has reviewed or the experience he has gained" because his methodology failed to include a review of the documents that would support his internal-protocols opinion. *Id.*

By contrast, Dr. Grier here is not attempting to testify that Ethicon followed its own internal design protocols or that they were otherwise adequate. As such, his opinion does not require a review of internal design protocols, design history files, or design failure modes and

effects analyses (dFMEA). Indeed, although Dr. Grier reviewed some of these documents, he explained that design documents are not clinically relevant to him and that dFMEAs do not fall within any level of the hierarchy of scientific evidence. Ex. 1, Grier 3/22/16 Dep. Tr. 44:20-24, 65:15-66:9, 136:9-23, 331:2-11. As a result, these are not the type of materials upon which Dr. Grier would rely to form his clinical opinion on the safety and efficacy of mesh products for use in patients.

At bottom, Dr. Grier has the expertise required to provide opinions on the safety and efficacy of the TVT, TVT-O, TVT-Secur, Prolift, and Prolene Soft Mesh designs, and has provided a reliable basis for those opinions. This opinion testimony is admissible.

II. Dr. Grier's Testimony About His Clinical Experience with TVT Products, Prolift, and Prolene Soft Mesh Is Admissible to Support His Opinion on the Safety and Efficacy of These Products.

A physician's "knowledge, experience, and review of scientific literature provide sufficiently reliable bases for his opinions under *Daubert*." *Eghnayem v. Boston Scientific Corp.*, 57 F. Supp. 3d 658, 714 (S.D.W. Va. 2014). This Court, in particular, has made clear that a physician can draw upon his clinical experience and review of relevant literature to give opinions on a product's safety and efficacy. *See Tyree*, 54 F. Supp. 3d at 585 (finding that a urologist with extensive clinical experience and relying on peer-reviewed literature could opine on the safety and efficacy of mesh products). It has found the same with respect to an expert offering a risk/benefit opinion. *See Winebarger*, 2015 WL 1887222, at *7.

As explained, Dr. Grier offers the same opinions here based on the same methodology. He seeks to testify that the benefits of the TVT, Prolift, and Prolene Soft Mesh products outweigh their risks and he bases that opinion on his extensive clinical experience, as well as his review of the relevant medical literature over the course of his career. Ex. 1, Grier 3/22/16 Dep.

Tr. 331:12-332:17, 334:10-13, 335:7-17, 336:11-20, 338:18-351:6; Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 1-2, 7-19, 22-24; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 1-2, 6-15, 17-19; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 1-2, 11-23, 25-30; Ex. E to Pls.' Mot. (Dkt. 2022-5), Grier TVT-Secur Report at 1-2, 11-27, 31-35. Dr. Grier's support for this opinion includes the complications he has seen in his practice with TVT, TVT-O, or TVT-Secur slings, which are similar to what is reported in the medical literature. Ex. 1, Grier 3/22/16 Dep. Tr. 334:10-13.

Plaintiffs take issue with Dr. Grier's opinion about incidence of complications he sees in his practice because it is not supported by any statistical analysis, formal study, or separate "list" for "tracking data." *See* Pls.' Mem. (Dkt. 2024) at 12. Plaintiffs cite no authority that this is required under *Daubert*. Instead, what Daubert requires, and what Dr. Grier did here, was to treat patients that have experienced complications, record those complications in medical records, and report on the incidence of those complications that he has seen in his practice. Contrary to Plaintiffs' argument, Dr. Grier follows his patients, the reason for any mesh removal, and the product being removed through annual appointments and medical records. Ex. 1, Grier 3/22/16 Dep. Tr. 143:3-13, 336:3-10. Any lack of separate "tracking data" does not render Dr. Grier's clinical experience unscientific or unhelpful.

A physician offering opinions based on complications the physician has observed in his or her clinical practice uses a reliable methodology, and is consistent with the analysis this Court employs for reliability. *Winebarger*, 2015 WL 1887222, at *7. Indeed, this Court has rejected the argument that opinions on mesh complications are unreliable because they are based on personal experience and review of medical literature. *See Eghnayem*, 57 F. Supp. 3d at 714 (denying

request to exclude Dr. Walmsley's general opinions on complication rates based on his personal clinical experience and review of the medical literature).

At bottom, Dr. Grier is sufficiently qualified and the opinions he seeks to offer result from a reliable methodology. It would make no sense, and is contrary to the Rules of Evidence, to allow Dr. Grier to draw upon clinical experience and medical literature to provide a risk/benefit opinion, but then prevent him from explaining to the jury how he reached that opinion.

III. Dr. Grier Is Qualified to Provide an Opinion on the Adequacy of the IFUs for the TVT Products, Prolift, and Prolene Soft Mesh.

"[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings." *Winebarger*, 2015 WL 1887222, at *15. A physician is qualified to make a comparison between "the risks he perceives that the [device] poses to patients" and whether the labels "convey these risks to physicians." *Id.* (finding Dr. Shull qualified to give opinions on product labeling based on his clinical experience because his testimony did not touch on regulatory issues).

Dr. Grier seeks to offer such an opinion here. In addition to his clinical experience with mesh surgical techniques and review of IFUs, Dr. Grier relies on his review of complications reported in the medical literature, statements of leading medical societies, FDA Device Labeling Guidance No. G91-1 (dated March 8, 1991), discussions with other surgeons, and general knowledge as a pelvic-floor surgeon. Ex. 1, Grier 3/22/16 Dep. Tr. 326:23-330:20, 332:13-333:23; Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 19-22; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 15-16; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 23-25; Ex. E to Pls.' Mot. (Dkt. 2022-5), Grier TVT-Secur Report at 28-30. Based

on this support, Dr. Grier has formed the opinion that exposure/erosion is the only risk unique to mesh devices, and that degradation, shrinking, contraction or pore collapse, roping or curling, particle loss, cytotoxicity, excessive inflammatory response, and carcinogenicity are ***not*** risks associated with mesh devices. Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 17, 19-22; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 15-16; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 18-21, 23-25; Ex. E to Pls.' Mot. (Dkt. 2022-5), Grier TVT-Secur Report at 19-20, 34. Dr. Grier further concludes that chronic pain and dyspareunia are generalized risks of mesh surgery, and therefore need not be warned about. Ex. 1, Grier 3/22/16 Dep. Tr. 19:12-21; 319:8-14, 332:18-25; 337:9-12. As a result, Dr. Grier concludes that there are no additional unique risks that should be included in the IFU warnings. Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 19-22; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 15-16; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 23-25; Ex. E to Pls.' Mot. (Dkt. 2022-5), Grier TVT-Secur Report at 28-29, 34. Dr. Grier's opinion is consistent with the legal principle that there is no duty to warn of risks commonly known to surgeons who use the device. 21 C.F.R. § 801.109(c) (information may be omitted from labeling for prescription device "if, but only if, the article is a device for which directions, hazards, warnings and other information are commonly known to practitioners licensed by law to use the device.").

This Court's rulings in *Tyree* and *Bellew* are distinguishable. In those cases, the Court excluded testimony from defense experts who offered opinions that the warnings were adequate merely because they included risks that the experts observed in their own practices. *See Tyree*, 54 F. Supp. 3d at 584 (S.D.W. Va. 2014), as amended (Oct. 29, 2014); *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Dkt. 265 at 33 (S.D.W. Va. Nov. 20, 2014). While a single physician's

experience may not be sufficient, it is sound methodology to rely upon a large pool of scientific literature and studies, combined with the clinical experience and evaluation of many physicians and medical organizations, to support a conclusion that certain risks do not occur and therefore need not be included in the IFU, as Dr. Grier has done here. Indeed, when Plaintiffs' experts have concluded that risks do occur based on such support, they are allowed to testify that the risk should have been included in the mesh warnings. It stands to reason that an expert employing this same methodology, while reaching a different conclusion, has also provided admissible testimony. That Plaintiffs may disagree with Dr. Grier's conclusion goes to weight, not admissibility.

Dr. Grier has the clinical experience needed to form an opinion about the warnings accompanying the mesh devices he uses in his patients. Ex. 1, Grier 3/22/16 Dep. Tr. 329:6-330:5. In his practice, he reviews IFUs before using a new medical device. *Id.* at 329:14-23. Dr. Grier has also performed hundreds of SUI and POP mesh surgeries and removed dozens of mesh devices from patients. *Id.* at 143:20-144:13, 145:23-146:11, 333:24-334:9; Ex. B to Pls.' Mot. (Dkt. 2022-2), Grier Prolift Report at 2; Ex. C to Pls.' Mot. (Dkt. 2022-3), Grier Prolene Soft Report at 2; Ex. D to Pls.' Mot. (Dkt. 2022-4), Grier TVT/TVT-O Report at 2. Based on his clinical perspective and review of the medical literature, he is qualified to give opinions about warnings.

At bottom, Dr. Grier is qualified to provide opinions on the IFUs and has employed a sufficiently reliable methodology. His opinion on the adequacy of the TVT, TVT-O, TVT-Secur, Prolift, and Prolene Soft Mesh IFUs is therefore admissible.

CONCLUSION

For the foregoing reasons, Ethicon respectfully requests that Plaintiffs' motion be denied in its entirety.

Respectfully submitted,

ETHICON, INC. AND
JOHNSON & JOHNSON

/s/ Rita A. Maimbourg
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5002
rita.maimbourg@tuckerellis.com

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
THOMAS COMBS & SPANN PLLC
300 Summers St.
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
Telephone: 304.414.1807
dthomas@tcspllc.com

/s/ Christy D. Jones
Christy D. Jones
BUTLER SNOW LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
Telephone: 601.985.4523
christy.jones@butlersnow.com

CERTIFICATE OF SERVICE

I certify that on May 9, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ *Rita A. Maimbourg*
Rita A. Maimbourg
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113-7213
Telephone: 216.592.5000
Facsimile: 216.592.5002
rita.maimbourg@tuckerellis.com